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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,943	02/22/2002	Dean Sadat-Aalaee	00537-191002	3207

7590 05/16/2003

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EXAMINER
RUSSEL, JEFFREY E

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 05/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/980,943	SADAT-AALAEE ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 February 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7,8,10 and 11* is/are rejected.

7)☒ Claim(s) *6 and 9* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5,6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

1. The abstract of the disclosure is objected to because of the presence of legal phraseology such as "said". Also, the Abstract requires more detail as to the particular pharmaceutical uses of the claimed peptides. Applicants should ensure that the Abstract does not exceed 150 words in length. Correction is required. See MPEP § 608.01(b).

2. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

3. The disclosure is objected to because of the following informalities: At page 2, lines 15, 18, and 21, and at pages 14 and 17, the status of the U.S. patent applications should be updated. Appropriate correction is required.

4. Claims 8 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 8 is incomplete because it does not set forth formula (I) in the body of the claim. A claim must be complete in and of itself, and Applicants have not shown that there is no other practical way to define the invention in words, e.g., by reciting formula (I) verbatim in the claim or by re-writing the claim so that it is dependent upon claim 1. See MPEP 2173.05(s). There is no antecedent basis in the claims for the phrase "said human or other

animal" at claim 11, line 4. Because this claim is drawn to in vitro imaging in cells, it is believed that the reference to humans and other animals was inadvertent.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

For the purposes of this invention, the level of ordinary skill in the art is deemed to be at least that level of skill demonstrated by the patents in the relevant art. Joy Technologies Inc. v. Quigg, 14 USPQ2d 1432 (DC DC 1990). One of ordinary skill in the art is held accountable not only for specific teachings of references, but also for inferences which those skilled in the art may reasonably be expected to draw. In re Hoeschele, 160 USPQ 809, 811 (CCPA 1969). In addition, one of ordinary skill in the art is motivated by economics to depart from the prior art to reduce costs consistent with desired product properties. In re Clinton, 188 USPQ 365, 367 (CCPA 1976); In re Thompson, 192 USPQ 275, 277 (CCPA 1976).

6. Claims 1-5, 7, 8, 10, and 11 are rejected under 35 U.S.C. 103(a) as being obvious over the WO Patent Application 98/24807. The WO Patent Application '807 teaches compounds of the formula set forth in claim 1 in which residue A^6 can be Abu, beta-Ala, Gaba, or Val (see claim 4). The WO Patent Application '807 also teaches a specific compound at page 38, line

23, which differs from Applicants' compound at claim 3, line 4, in that the compound of the reference has an Abu rather than a Gaba residue at the position corresponding to A^6, and teaches a specific compound at page 39, line 31, which differs from Applicants' compounds of claim 4 in that the compound of the reference has a Val rather than a Gaba or beta-Ala residue at the position corresponding to A^6. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to substitute a Gaba residue for the Abu residue in the WO Patent Application '807's compound at page 38, line 23, because Applicants' claimed compounds are generically encompassed by the formula of the WO Patent Application '807's claim 1; because the WO Patent Application '807 discloses these residues to be equivalents at this position; because the Gaba and Abu residues are isomers of one another; and because the resultant somatostatin analogs have the same imaging utility disclosed by the WO Patent Application '807. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to substitute a Gaba or beta-Ala residue for the Val residue in the WO Patent Application '807's compound at page 39, line 31, because Applicants' claimed compounds are generically encompassed by the formula of the WO Patent Application '807's claim 1; because the WO Patent Application '807 discloses these residues to be equivalents at this position; and because the resultant somatostatin analogs have the same imaging utility disclosed by the WO Patent Application '807. The WO Patent Application '807 teaches that its somatostatin analogs can be used to image cells in vitro and in vivo (see, e.g., page 24, lines 18-23). Applicants have stated in their specification that their claimed compounds have unexpected agonist as opposed to antagonist activities (see, e.g., page 2, lines 14-22, of Applicants' specification). However, in the absence of a probative comparison of the closest prior art

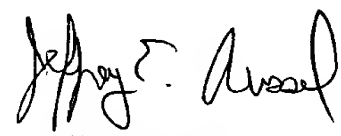
compounds of the WO Patent Application '807 and of Applicants' claimed compounds in the same assay, Applicants' statement in and of itself can not be relied upon to rebut the prima facie case of obviousness set forth above. No comparative evidence commensurate in scope with Applicants' claims is present in the specification. With respect to instant claim 8, the WO Patent Application '807 does not teach using its somatostatin analogs to treat cancer cachexia or decreasing body weight. However, the WO Patent Application '807 does disclose that its compounds are useful for promoting the release of growth hormone (see, e.g., page 25, lines 22-25). It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to administer the somatostatin analogs of the WO Patent Application '807 to humans or other animals with cancer cachexia or decreasing body weight because the somatostatin analogs' disclosed ability to promote growth hormone release would have been expected to be useful in counteracting cancer cachexia and decreasing body weight, and because it is routine to use somatostatin antagonists for the same purposes that other somatostatin antagonists are used.

7. Claims 6 and 9 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Because the WO Patent Application 98/24807 describes its compounds as somatostatin antagonists, there would be no motivation to administer the claimed compounds so as to elicit a somatostatin agonist response in a human or other animal. Because the WO Patent Application 98/24807 describes its compounds as promoting the release of growth hormone or insulin, there would be no motivation to administer the claimed compounds so as to inhibit the release of growth hormone or insulin in a human or other animal. The WO

Patent Application '807 does not teach or suggest that its somatostatin analogs would have any ability to inhibit the secretion of glucagon or other pancreatic exocrine secretions in a human or other animal.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (703) 308-3975. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback can be reached at (703) 306-3220. The fax number for Art Unit 1654 for formal communications is (703) 305-3014; for informal communications such as proposed amendments, the fax number (703) 746-5175 can be used. The telephone number for the Technology Center 1 receptionist is (703) 308-0196.



Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

May 15, 2003